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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/853,343	05/10/2001	Allan Bradley	11635-005001 / OTA 00-43	8644

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EXAMINER	
CHUNDURU, SURYAPRABHA	

ART UNIT	PAPER NUMBER
1637	

DATE MAILED: 02/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/853,343	BRADLEY ET AL.	
	Examiner	Art Unit	
	Suryaprabha Chunduru	1637	

S.M

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 September 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-57 and 82-103* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-57 and 82-103* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicants' response to the office action filed on September 30, 2003 has been entered.

2. This application has a filing date as May 10, 2001 and claims priority to a nonprovisional application 09/071,876 (now a US patent 6, 048, 695) filed on May 4, 1998.

3. Claims 1-57 and 82-103 are pending.

New Grounds of Rejections

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-22, 82-83, 86-93, 95-101 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The instant claims are indefinite and unclear because the claims 1, 82-83, 86-88, 95 recite "R_2 comprises alkoxysaline group soluble in solution". It is unclear whether the compound having the formula R_1-X-R_2 is soluble in solution or only the R_2 comprising alkoxysaline is soluble in solution.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

A. Claims 1-7, 12-15, 18-19, 84-85, 88-91 are rejected under 35 U.S.C. 102(b) as being anticipated by Plueddemann (USPN. 4,231,910).

Plueddemann teaches a modified biological molecule (primer compositions) a composition of the instant claims 1-7, 84-85, 88, wherein Plueddemann teaches that the composition comprises a nucleic acid (DNA) covalently bound to a compound having the formula R_1-X-R_2 wherein R_1 is a cyclic ether group (epoxy group), R_2 is an alkoxysilane group and X is a moiety linking cyclic ether group and the alkoxysilane group (see column 2, lines 21-28) and the cyclic ether group comprises epoxide group (ethylene oxide) and alkoxysilane comprises trimethyloxysilane (see column 2, lines 22-28); alkoxysilane or organosilane comprising compounds are soluble in solution (see column 3, lines 1-14).

With regard to claims 12-15, 90-91, Plueddeman also teaches that a biological molecule is an oligonucleotide which reacts with the R_1 group at 5' end (primer, DNA) (see column 2, lines 5-35);

With regard to claim 19, Plueddeman also teaches that the compound is 3-glycidoxy propyltrimethoxysilane (see column 2, lines 23-24). Thus the disclosure of Pluddemann meets the limitations in the instant claims.

B. Claims 1-9, 11-15, 18, 20-36, 38-39, 47, 82-91, 94-97, 99-103 are rejected under 35 U.S.C. 102(e) as being anticipated by Beattie (USPN. 6,426,183).

Beattie teaches a composition of claims 1-7, 18, 21, 23, 82-88, 102-103, comprising a nucleic acid or a modified biological molecule (nucleic acid) wherein Beattie teaches that the composition comprises biological molecule covalently bound to a compound having formula R_1-X-R_2, wherein R_1 is a cyclic ether group or an amino group, R_2 is an alkoxysilane group, X is a linking moiety, and the compound cyclic ether group contains epoxy group (see column 18, lines 52-65).

With regard to claims 8-9, 11-15, 30-36, 38-39, 47, 94-101, Beattie also teaches that the biological molecule comprises compounds such as oligonucleotides, peptides, polypeptides, proteins, hormones, antibodies, catalyst molecules, carbohydrates and other organic compounds (see column 14, lines 3-11, column 16, lines 48-67, column 17, lines 1-5, column 18, lines 52-65); With regard to claims 20, 29, 39, 86-91, Beattie also teaches that the 5' amino or 3'amino-propanol nanomers are attached to epoxysilinized substrate, and that the 3'-amino propanol-derivatized oligonucleotide and underivatized glass is a covalent bond, more specifically an ester linkage produced through the hydroxyl group (see column 16, lines 48-66).

With regard to claims 22- 28, Beattie et al. also teach that the substrate includes a glass, quartz, (see column 4, lines 33-36, column 9, lines 40-57) with oxide surfaces like leaded glass (see column 9, lines 50-57) or polyethylene surfaces (see column 8, lines 58-67). Thus the disclosure of Beattie meets the limitations in the instant claims.

C. Claims 1-6, 10, 18-19, 23, 37 are rejected under 35 U.S.C. 102(b) as being anticipated by Rauh et al. (5,401,415).

Rauh et al. teach a composition of claims 1-6, 10, 18, 23, 37, comprising a lipid molecule, wherein Rauh et al. teach that the composition or a modified biological molecule covalently bound to a compound having formula R_1-X-R_2, wherein R_1 is a cyclic ether group/ or an amino group, R_2 is an alkoxysilane group, X is a linking moiety, and the compound cyclic ether group contains epoxy group (see column 6, lines 26-67, column 7, lines 15-52).

With regard to claim 19, Rauh et al. also teach that the compound is 3-glycidoxypropyl trimethoxysilane, which is soluble in solution (see column 9, lines 9-16). Thus the disclosure of Rauh et al. meets the limitations in the instant claims.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 16-17, 40-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Beattie (USPN. 6,426,183) in view of Lockhart et al. (USPN. 6,040,138).

Beattie teaches a composition comprising a nucleic acid or a modified biological molecule (nucleic acid) wherein Beattie teaches that the composition comprises biological molecule covalently bound to a compound having formula R_1-X-R_2, wherein R_1 is a cyclic ether group or an amino group, R_2 is an alkoxysilane group, X is a linking moiety, and the compound cyclic ether group contains epoxy group (see column 18, lines 52-65). Beattie also teaches that the biological molecule comprises compounds such as peptides, polypeptides, proteins, hormones, antibodies, catalyst molecules, carbohydrates and other organic compounds (see column 14, lines 3-11, column 16, lines 48-67, column 17, lines 1-5, column 18, lines 52-65); the

5' amino or 3'amino-propanol nanomers are attached to epoxysilinized substrate, and that the 3'-amino propanol-derivatized oligonucleotide and underivatized glass is a covalent bond, more specifically an ester linkage produced through the hydroxyl group (see column 16, lines 48-66). However, Beattie did not teach nucleic acid comprising chromatin structure nucleic acid from a tumor cell and normal, cloning vehicle, array comprising more than 400 clusters per square centimeter.

Lockhart et al. teach high-density gene array, wherein Lockhart et al. teach that the gene array comprising oligonucleotides greater than 1000 or more spotted on a surface at predetermined locations (see column 19, lines 18-36, column 2, lines 36-67, column 3, lines 1-29). Lockhart et al. also teach detecting and comparing or calculating relative gene expression levels in comparison to controls (see column 10, lines 22-29, lines 59-61). Lockhart et al. also teach that this array can be used to quantify a gene (part of chromosome) expression, associated to a disease conditions such as cancers, screening cDNA libraries for target gene expression (see column 4, lines 54-67, column 5, lines 1-12, column 26, lines 14-41); cloning vehicle (see column 13, lines 20-35); a kit comprising an array of immobilized oligonucleotides, and include instructions describing the use of the array (see column 5, lines 62-67, column 6, lines 1-11). Therefore, it would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made, to improve the array as taught by Beattie by further including high density array which is used for massive parallel screening of target genes as taught by Lockhart et al. to achieve the expected advantage of developing a high-throughput array for screening for target genes An ordinary practitioner would have been motivated to improve the array of Beattie with the inclusion of the gene array of Lockhart et al. because the method of Lockhart et al.

would provide a high-throughput array for determining and comparing a large number of cellular gene targets simultaneously at a given time.

Response to arguments

7. Applicants' response to the office action is fully considered and found persuasive in part.

8. With reference to the rejections under obviousness double-patenting and provisional double-patenting, Applicants arguments and terminal disclaimer are fully considered and the rejection is with drawn herein in view of the Terminal Disclaimer.

9A. With regard to the rejection made in the previous office action under 102(b) (Krinski et al. Applicants' arguments and amendment are fully considered and found persuasive and the rejection is withdrawn herein for the instant claims 1-3 and 18-19, 84-87 in view of the amendment and arguments.

9B. With regard to the rejection made in the previous office action under 35 USC 102(e) anticipated by Beattie (USPN. 6,426,183), Applicants' arguments and amendment are fully considered and found not persuasive and the rejection is maintained herein Applicants argue that Beattie et al. did not teach a cyclic ether group. The argument is fully considered and found not persuasive. Beattie et al. teach at least one amino or at least one hydroxyl group reacts with silane-containing substrate (see column 2, lines 18-42) and the reaction is facilitated using epoxysilanized glass (see column 16, lines 48-66), which indicates that epoxy silane contains cyclic ether group. Further alkoxysilane group of the epoxysilane is soluble in solution. Further, Applicants argue that Beattie et al. did not teach an article of manufacture comprising biological molecules modified before attachment to a surface This argument is found not persuasive because Beattie discloses on column 16, lines 48-66, that the 5' amino or 3'amino-propanol

nanomers are attached to epoxysilinized substrate, and that the 3'-aminopropanol-derivatized oligonucleotide and underivatized glass is a covalent bond, more specifically an ester linkage produced through the hydroxyl group, which indicates that the modified biological molecule is modified before attachment on to a substrate. Thus the disclosure of Beattie meets the limitations in the instant claims. The rejection is rewritten as above to include other claims which also meet the teachings of Beattie.

9C. With regard to the rejection of claims 1-3, 11-15, 18, 20, 22, 84-91, 95, 100-102 in the previous office action under 35 U.S.C. 102(e) as being anticipated by Gray et al. (USPN. 5,851, 769). Applicants' arguments and amendment are fully considered and found not persuasive. Applicants argue that Gray et al. did not teach that an alkoxysilane is soluble in solution. This argument is fully considered and found not persuasive. Because examiner notes that alkosilane of the instant claims is same as the alkosilane group of the teachings of Gray et al. and would have the same inherent properties, that is, same solubility property. The amendment reciting "soluble in solution" is an inherent property of alkoxysilane since the structure is same. It is noted that It is noted that as MPEP 2112 states, "Products of identical chemical composition can not have mutually exclusive properties." A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). In the instant case since both structures are identical (that of the claimed invention and of Gray et al.) and yield the same result. Examiner notes that 95 is not dependent on claims 86-88. Thus the rejection for claims 1-3, 11-15, 18, 20, 22, 95, 100-101 is

maintained. With regard to claims 84-91, applicants' amendment obviated the rejection because the amended claims comprise no amino group.

Conclusion

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 571-272-0783. The examiner can normally be reached on 8.30A.M. - 4.30P.M, Mon - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and - for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Suryaprabha Chunduru
February 18, 2004

JEFFREY FREDMAN
PRIMARY EXAMINER